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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER				
KISH, JAMES M				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/687,522

Applicant(s)

SEPPI ET AL.

Examiner

JAMES KISH

Art Unit

3737

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 and 56-73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-47 and 56-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Response to Arguments

Applicant's arguments filed September 16, 2008 have been considered but they are not persuasive.

The Applicant argues that Ogawa is concerned with eliminating 3 bone images to highlight soft tissue without contrast agents. Hughes' teachings of creating a high fidelity picture of the entire circulatory tree. Also, Acharya teaches viewing and analyzing the soft tissue portion of non-calcified plaque. The Applicant therefore concludes that there is no obvious reason to combine any of these prior art. The Examiner respectfully disagrees.

Ogawa teaches all of the claimed subject matter with exception of the use of a contrast agent, as previously stated in the prior Office Action. This means that Ogawa teaches energy subtraction processing performed on projection image signals of different energy bands. Several 2-D images may be used to create a 3-D image. The object is thus formed such that a pattern of a specific structure (or the region of interest (ROI)) having low contrast, such as a diseased part in the object, can be detected easily. See the Abstract.

Hughes teaches angiography imaging. The specific type of angiographic imaging procedure being performed comprises creating at least two signals at first and second selected wavelengths or energy levels through selected blood vessels and subtracting the two signals. Due to the K-absorption edge of the contrast agent the

resulting signal will emphasize the blood vessel (or the ROI) containing the contrast agent. See the Abstract.

Acharya teaches a method of plaque characterization comprising obtaining first and second image data at a first and second x-ray energy. The method also comprises subtracting these data set to create a third data set.

Therefore, the prior art of record are all related to a similar methodology of imaging and it would have been obvious to one of ordinary skill in the art to inter-relate specific teachings, i.e., use of a contrast agent (or the lack thereof), in order to obtain an image of a particular body structure under investigation (for instance, soft tissue, blood vessels, etc.).

For at least the reasons above, the rejection of the Office Action dated June 16, 2008 still stands and is repeated below.

Claim Objections

Claims 70 and 72 are objected to because of the following informalities:

Claims 70 and 72 are objected to for failing to set forth further structural limitations from the claims from which they depend.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29, 32-33, 36-37, 40, 43, 45-47, 66-67 and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by Ogawa et al. (US Patent No. 6,278,760). Ogawa discloses a system and method wherein cone-like radiation is irradiated from each of different directions of projection to an object, and projection image signals of different energy bands are acquired with respect to the object and each of the different directions of projection. Energy subtraction processing is performed on the projection image signals of the different energy bands. A three-dimensional image or a tomographic image of the object is formed from the energy subtraction-processed projection image signals (see Abstract). Also see column 3, lines 1-41 and column 4, lines 45-50.

Regarding claim 37, the modification is the volume signal forming means of Figure 2.

Regarding claims 43 and 45-47, see column 6, lines 21-67.

Regarding claim 66, see column 8, lines 5-20 (and/or Figure 2) of Ogawa.

Regarding claim 67, see column 5, lines 47-65 (and/or Figure 1) of Ogawa.

With regard to the claim amendment of claim 29, the use of (or lack of) a contrast agent does not alter the set of stored instructions on the computer product.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 4-7, 10-14, 17-33, 36-40, 43-47, 56-59, 61-68, 70 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa et al. in view of Hughes et al. (US Patent No. 4,432,370). Ogawa discusses the phenomenon of separating structures and substances based on having different radiation absorptivity (similar to dichromography), however, Ogawa does not explicitly describe the use of a contrast agent.

In a similar field of endeavor, Hughes teaches producing an x-ray image for a blood vessel by directing synchrotron radiation at first and second selected energy levels through the vessel, detecting the attenuated radiation and logarithmically

subtracting the two signals. Also see column 2, lines 36-45, where digitizing the images is described. Other elements such as samarium or europium can be used as contrast agents (column 5, lines 60-64). Also see column 1, line 66 through column 2, line 7. it would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a contrast agent into the system and methods of Ogawa in order to create a high fidelity picture of the entire circulatory tree (column 2, lines 9-10 of Hughes).

Regarding claims 62 and 64, see column 8, lines 5-20 (and/or Figure 2) of Ogawa.

Regarding claims 63 and 65, see column 5, lines 47-65 (and/or Figure 1) of Ogawa.

Regarding claims 68, 70 and 72, see Ogawa, column 2, lines 1-6 where diagnosis of an illness is discussed.

With regard to claims 29, 32-33, 36-37, 40, 43, 45-47, 66-67 and 72, in the situation where the Applicant disagrees with the interpretation that the use of (or lack of) a contrast agent does not alter the set of stored instructions on the computer product, these claims are rejected over Ogawa in view of Hughes because Hughes teaches the use of contrast agents.

Claims 1, 6-10, 14, 17, 19-21, 29, 32-37, 39-40, 43, 45-47, 56-57, 60-68, 70 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa et al. in view of Acharya et al. (US Patent No. 6,922,462).

Ogawa discusses the phenomenon of separating structures and substances based on having different radiation absorptivity (similar to dichromography), however, Ogawa does not explicitly describe the use of a contrast agent.

In a similar field of endeavor to that of Ogawa, Acharya teaches a system and method of plaque characterization. The method comprises obtaining a first and second set of image data at a first and second energy level and calculating a third set of image data by subtracting each second pixel element from the corresponding first pixel element (see Abstract). The method may be performed on several imaging modalities (column 4, lines 6-14). See column 4, lines 60-66 concerning different orientations. Column 6, lines 13-37 describes an embodiment of Acharya of imaging without a contrast agent, much like that of Ogawa. Column 6, lines 18-52 describes a similar procedure, except with the use of a contrast. It would have been obvious to one of ordinary skill in the art to utilize a contrast agent in the methods and systems of Ogawa in order to view and analyze the soft tissue portion of non-calcified plaque (column 6, lines 51-52 of Acharya).

Regarding claims 62 and 64, see column 8, lines 5-20 (and/or Figure 2) of Ogawa.

Regarding claims 63 and 65, see column 5, lines 47-65 (and/or Figure 1) of Ogawa.

Regarding claims 68, 70 and 72, see Ogawa, column 2, lines 1-6 where diagnosis of an illness is discussed.

With regard to claims 29, 32-33, 36-37, 40, 43, 45-47, 66-67 and 72, in the situation where the Applicant disagrees with the interpretation that the use of (or lack of) a contrast agent does not alter the set of stored instructions on the computer product, these claims are rejected over Ogawa in view of Acharya because Acharya teaches the use of contrast agents.

Claims 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa et al. in view of Trauernicht (US Patent No. 5,629,968). Ogawa is previously described in the rejection of claim 40. However, there is no discussion of the manner in which the images are initially detected. Trauernicht discloses an apparatus and method for obtaining radiographic images of an object. Figure 3 shows two detectors separated by a beam stop device. The first detector receives the entire radiation dose. The beam stop "deactivates" certain lines of the second detector by not allowing those radiation beams to pass through it. These two images may be combined in registration to provide a composite image of enhanced quality relative to that of the two components (column 5, lines 8-23 and lines 44-49). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a beam stop, as taught in Trauernicht, in the system of Ogawa to prevent certain lines of radiation to proceed to a detector in order to gain a composite image with enhanced quality.

Claims 3 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa et al. in view of Hughes et al., as applied to claims 1 and 14 above, and further in view of Trauernicht. Ogawa in combination with Hughes is previously described. However, there is no discussion of the manner in which the images are initially detected. Trauernicht discloses an apparatus and method for obtaining radiographic images of an object. Figure 3 shows two detectors separated by a beam stop device. The first detector receives the entire radiation dose. The beam stop "deactivates" certain lines of the second detector by not allowing those radiation beams to pass through it. These two images may be combined in registration to provide a composite image of enhanced quality relative to that of the two components (column 5, lines 8-23 and lines 44-49). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a beam stop, as taught in Trauernicht, in the system of Ogawa in view of Hughes to prevent certain lines of radiation to proceed to a detector in order to gain a composite image with enhanced quality.

Claims 69, 71 and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa in view of Hughes as applied to claims 1, 22 and 29 above, and further in view of Keyes et al. (US Patent No. 4,482,918) – herein referred to as Keyes. Ogawa in combination with Hughes teaches all of the claimed subject matter except for the time-resolved kinetics of the contrast agent. Fig. 3 of Keyes illustrates a plot of how concentration of an x-ray contrast medium in a blood vessel would vary with time. Based on this information the imaging would be sequenced around the concentration to

acquire specific contrast exposures. It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of Keyes in the methods and systems of Ogawa and Hughes in order to determine the concentration of iodine in the vessels of interest at key moments in order to acquire the best possible images for the diagnosis.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **JAMES KISH** whose telephone number is (571)272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth S. Smith/
Primary Examiner, Art Unit 3737

JMK